

## **REMARKS**

### **Pending Claims**

Claims 1-64 are pending. Upon entry of the instant amendment and response, claims 1-64 are cancelled and claims 65-91 are presented for examination. The amendment does not introduce new matter and is made without any intention to abandon the subject matter as filed, but with the intention that claims of the same, greater, or lesser scope may be filed in a continuing application. The amendment does not introduce new matter. Support for the amendment may be found at least at pages 20, 30, 34, 80-100, Figures 1-33, and in the claims as originally filed.

### **Objections to the Specification**

The Examiner has objected to the application for including an abstract which comprises three paragraphs. Applicants respectfully submit that by their amendment, which provides an abstract in the form of a single paragraph, this objection is overcome. Applicants therefore respectfully request that the objection be reconsidered and withdrawn.

### **Rejection of Claims Under 35 U.S.C. § 101**

The Examiner has rejected claims 1, 8-15, 21-30, and 36-43 over the recitation of “a protein having ...” or “a DNA encoding the amino acid sequence.” The Examiner asserts that

the claims encompass the protein and DNA as they occur in nature. Applicants respectfully submit that the rejection is moot in view of the cancellation of these claims, and the addition of new claims which recite that the protein and DNA molecules, respectively, are "isolated."

**Rejection of Claims Under 35 U.S.C. § 112 First Paragraph: Enablement**

Claims 1, 12, 21, 23-24, 26-31, and 36-44 are rejected under 35 U.S.C. § 112 first paragraph. The Examiner acknowledges that the specification is enabling for an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO 1 or SEQ ID NO. 11, a fragment of the polypeptide of SEQ ID NO 1 comprising amino acid residues 72-316 or 76-316 and a method of recombinantly making these polypeptides but is not enabling for "all possible proteins having the activity and features recited in claim 1, or a polynucleotide having 70% or more homology to the polynucleotide of SEQ ID Nos 1 or 12 or 'all possible' polynucleotides encoding the polypeptides of SEQ ID NO.'s 1-11."

Applicants respectfully submit that the rejection is moot in view of the cancellation of claims 1-64. Moreover, the claims are amended to recite language approved by the U.S. Patent and Trademark Office (see, e.g., U.S. Patent 5,843,678 to Boyle, cited by the Examiner in the previous Office Action). However, to the extent that the rejection might be applied to the newly added claims, Applicants traverse the rejection for the following reasons.

The test of enablement is whether one skilled in the art could make or use the claimed invention from the disclosures in the patent application, coupled with information known in the art, without undue experimentation. United States v. Techtronics, Inc., 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988); In re Stephens, 529 F.2d 1343, 188 USPQ 659 (CCPA 1976). A patent need not teach, and preferably omits, what is well known in the art. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. M.I.T. v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). In order to make an enablement rejection, the Examiner has the initial burden to establish a

reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993). As stated by the court in In re Marzochi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971), “it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain it doubts the truth or accuracy of any statement in a supporting disclosure and *to back up its assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement*. 169 USPQ at 370 (emphasis added). See, MPEP 2164.04.

Applicants respectfully submit that the Examiner has not met her burden of proof to establish that Applicants’ disclosure does not enable the breadth of the claims. Contrary to the Examiner’s assertion, Applicants are not required to disclose *all* possible embodiments that could be encompassed by a genus (See MPEP 2164.08(b)). The standard of enablement is met where sufficient guidance is provided to enable “a skilled person ...to determine which embodiments...would be inoperative or operative with expenditure of no more effort than is normally required in the art.” See, Atlas Powder Co. v. E.I. du Pont Nemours & Co., 750 F.2d 1569, 1577, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984). In the instant case, Applicants’ specification discloses the protein and nucleic acid sequences of both mouse and protein homologs of OCIF Binding Molecule (OBM) and provides detailed instructions regarding how to isolate additional proteins and nucleic acids based on homology to these sequences. Procedures for making variants of proteins and nucleic acids are also disclosed in the specification and are well known in the art (see, as discussed at pages 53-55 of the Revised Interim Written Description Guidelines Training Materials). Applicants further provide a detailed description of assays which may be used to identify proteins and nucleic acids having the biological activity recited by the claims (see pages 52-100 of Applicants’ specification). Finally, as discussed above, nearly identical language has been considered to be enabled in U.S. Patent 5,843,678 to Boyle, which has been cited by the Examiner in the previous Office Action. Accordingly, Applicants respectfully submit that in view of the above arguments that the rejection is improper and should be reconsidered and withdrawn.

**Rejection of Claims Under 35 U.S.C. § 112 First Paragraph: Written Description**

Claims 21-23, 30, 36, and 43, are rejected under 35 U.S.C. § 112 First Paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time that the application was filed, had possession of the claimed invention. The Examiner asserts that written description is not commensurate in scope with claims drawn to variants or analogues of proteins with the amino acid sequences set forth as SEQ ID NO. 1 or SEQ ID NO. 11 as recited in the rejected claims.

Applicants respectfully submit that the rejection is moot in view of the cancellation of claims 1-64. However, to the extent that the rejection would be applied to any of the newly added claims, Applicants respectfully traverse the rejection. As amended, only claims 70 and 71 recite the terms “analogs” and “variants.” These claims further require that the proteins possess structural attributes relating to specifically disclosed sequences, and possess functional attributes (e.g., the ability to bind to OCIF). Applicants respectfully submit that this complies with the Written Description Guidelines currently set forth by the Office (see, as discussed at pages 53-55 of the Revised Interim Written Description Guidelines Training Materials) which acknowledges that methods of obtaining protein variants are routine in the art. Applicants’ therefore respectfully submit, that in view of the above amendment and arguments, that the rejection is improper and should be reconsidered and withdrawn.

**Rejection of Claims Under 35 U.S.C. § 102(e)**

Claims 1, 8-16, 21-31, 36, 39-41, 43-44 are rejected under 35 U.S.C. § 102(e) as being unpatentable over U.S. Patent 5,843,678, to Boyle, filed April 16, 1997 (hereafter, “Boyle”).

The Examiner asserts that the polynucleotide disclosed by Boyle shares 100% identity to SEQ ID No. 2 and encodes a polypeptide which is 100% identical to the polypeptide of SEQ ID NO 1.

Applicants respectfully submit that the rejection is moot in view of the cancellation of claims 1-64. However, to the extent that the reference is applied to any of Applicants' new claims, Applicants respectfully traverse the rejection. Applicants' earliest effective priority is to Japanese Patent Application 97808/1997, filed April 15, 1997, a certified English translation of which was provided to the U.S. Patent and Trademark Office with the filing of this Application on December 15, 1998 and acknowledged by the Examiner in the Office Action Summary Sheet mailed on February 25, 2000. As indicated in certified translation, Applicants had disclosed OCIF-binding proteins (OBMs) in the April 15, 1997-filed Japanese Patent Application. Applicants therefore respectfully submit that in view of Applicants' perfection of their priority claim, the reference to Boyle cannot be properly applied with respect to the protein claims and should be reconsidered and withdrawn. With respect to the nucleic acid claims now pending, Applicants respectfully submit that the rejection is no longer appropriate, as Applicants have amended the claims to delete the reference to SEQ ID NO. 2. Applicants therefore respectfully request that in view of the above arguments and amendments that the rejection should be reconsidered and withdrawn.

**Rejection of Claims Under 35 U.S.C. § 112 second paragraph.**

Claims 1, 12, 21, 23-24, 26-31, and 36-44 are rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner objected to a number of claim terms as detailed at pages 10-12 of the Office Action.

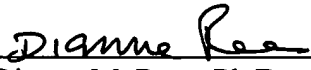
Applicants respectfully submit that the rejection is moot in view of the cancellation of claims 1-64. Because the new claims do not contain the objected-to language, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**CONCLUSION**

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned agent of record.

Respectfully submitted,

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